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No. ———

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

THOMPSON MEDICAL COMPANY, INC.,
Petitioner,

v.

FEDERAL TRADE COMMISSION,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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QUESTIONS PRESENTED FOR REVIEW

1. May a court of appeals affirm a cease and desist order of the Federal Trade Commission that has been challenged as unsupported on the record without at all reviewing the record and determining that the order is supported by substantial evidence on the record as a whole?

2. May the FTC issue a vague order that may prohibit the dissemination of even truthful and non-deceptive product information?

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[1] The caption identifies all parties to this action. Thompson Medical Company has no parents, subsidiaries or affiliates.

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REFERENCE TO OPINIONS BELOW

The opinion of the Court of Appeals for the District of Columbia Circuit, reported at 791 F.2d 189, —— U.S. App. D.C. —— (1986), appears as Appendix A at pages 1a-35a.

The opinion of the Federal Trade Commission, reported at 104 F.T.C. 648, 786 (1984) appears as Appendix B at pages 36a-245a. The final order of the Federal Trade Commission, reported at 104 F.T.C. 648, 842, appears as Appendix C at pages 246a-55a. The initial decision of the ALJ, reported at 104 F.T.C. 648, 660, appears as Appendix D at pages 256a-678a.

JURISDICTION OF THIS COURT

The judgment of the court of appeals was entered on May 27, 1986, and appears as Appendix E at pages 679a-80a. Thompson's petition for rehearing and suggestion for rehearing en banc were denied by the court of appeals on August 25, 1986, and the court's orders appear as Appendix F at pages 681a-84a.

This Court has jurisdiction to review this matter by writ of certiorari pursuant to 28 U.S.C. § 1254(1).

APPLICABLE CONSTITUTIONAL PROVISIONS AND STATUTES

The First Amendment to the Constitution provides, in relevant part:

> Congress shall make no law . . . abridging the freedom of speech . . . ."

Section 706 of the Administrative Procedure Act, 5 U.S.C. § 706, provides in relevant part:

> The reviewing court shall—
>
> . . . .
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege, or immunity;
>
> . . . .
>
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute . . . .
>
> In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, provides in relevant part:

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful.

* * * *

(c) Review of order; rehearing

Any person, partnership, or corporation required by an order of the Commission to cease or desist from using any method of competition or act or practice may obtain a review of such order in the court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation resides or carries on business, by filing in the court, within sixty days from the date of the service of such order, a written petition praying that the order of the Commission be set aside. . . . Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the Commission until the filing of the record and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the Commission . . . . The findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

* * * *

(d) Jurisdiction of court

Upon the filing of the record with it the jurisdiction of the court of appeals of the United States to affirm, enforce, modify, or set aside orders of the Commission shall be exclusive.

STATEMENT OF THE CASE

In this case, the Federal Trade Commission issued a broad cease and desist order against Thompson Medical Company ("Thompson") which adopted a new standard severely restricting the type of data that can be relied

upon to provide a reasonable basis for over-the-counter drug advertising claims. The new standard, based on factual findings that were not reviewed by the court of appeals, would brand as deceptive and prohibit the dissemination of any statement that an OTC analgesic was effective absent rigorous scientific data of a specific, narrow type—regardless of how true, how well-explained, and how well-supported with other data, in short, how non-deceptive, the statement.

Thompson, manufacturer of Aspercreme, the product involved in this case, seeks review in this Court of the total failure of the United States Court of Appeals for the District of Columbia Circuit (Robinson, Mikva and Ginsburg, JJ.) to review the record underlying the FTC's key factual findings. The court of appeals abdicated its well-established judicial responsibility to undertake a "thorough, probing, in-depth review" [1] of agency action to ensure that adjudicative findings are supported by substantial evidence on the whole record,[2] a responsibility that has been placed, by Congress, "in the keeping of the Courts of Appeals." [3] The court of appeals has thus granted the FTC a broad license to apply its new substantiation standard in future OTC drug cases free from judicial scrutiny and without any prior notice to manufacturers as to when it will apply.

Thompson also seeks review of the vagueness and breadth of the order which prohibits any advertisement implying that any OTC analgesic drug is effective for the relief of minor pain or other symptoms of any musculoskeletal disorder unless Thompson is able to support the efficacy of the product with "at least two adequate and

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[1] *Citizens To Preserve Overton Park, Inc. v. Volpe,* 401 U.S. 402, 415 (1971).

[2] *Universal Camera Corp. v. NLRB,* 340 U.S. 474, 488 (1951).

[3] *FTC v. Standard Oil Co.,* 355 U.S. 396, 401 (1958) (quoting *Universal Camera,* 340 U.S. at 491).

well-controlled, double blinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons, independently of each other." [4] At oral argument, not even FTC counsel could assert with any assurance what the order would prohibit and what it would allow.[5] The order will inhibit, and can be read to prohibit totally, absent a very limited type of scientific proof, any statement linking Aspercreme with the relief of minor arthritis pain no matter how true and how well qualified the statement, even if it makes no express or implied representation that scientific data support the statement.

Aspercreme, Thompson's brand of trolamine salicylate, is offered as a topical rub for the temporary relief of minor arthritis pain. The analgesic agent in trolamine salicylate, like the primary analgesic agent in aspirin, is salicylate, which is universally recognized to be effective. Unlike aspirin, which is swallowed, digested and passed through the bloodstream, the salicylate in Aspercreme is delivered through the skin to the painful underlying areas.

Trolamine salicylate rubs have been sold in the United States since 1954 and are frequently recommended by physicians, pharmacists and other health care professionals for the relief of minor arthritis pain. Aspercreme has become the second leading external analgesic with 16.8% of the external analgesic market. Appendix D at 349a. Ben-Gay, a brand of methyl salicylate, dominates the market, controlling about 40% of external analgesic sales. *Id.*

Prior to purchasing Aspercreme, Thompson consulted with several outside experts, who advised Thompson that Aspercreme was safe and effective and who reviewed

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[4] Appendix C at 251a-54a.

[5] *See* pages 21-22, *infra*. A transcript of the oral argument before the court of appeals appears as Appendix G at pages 685a-751a.

studies concerning the penetration of trolamine salicylate below the skin. Since that time, Thompson has reviewed and commissioned numerous controlled scientific studies which indicate that trolamine salicylate is effective and that it penetrates the skin to deliver salicylate to affected areas. Thompson has received more than 65,000 voluntary communications from consumers in which over 95% reported that Aspercreme provided pain relief and that they intended to repurchase, a response that one expert described as "astounding," given that consumer complaints are far more common than consumer compliments. Further, more than 83% to 1,230 medical practitioners and health care professionals surveyed by another trolamine salicylate producer found the product effective for the relief of minor arthritis pain.[6]

Thompson has advertised Aspercreme as a safe, effective alternative to aspirin for the relief of certain minor arthritis pain. Thompson has also advertised that Aspercreme does not cause the known side effects that may result from the ingestion and systemic distribution of aspirin. There is no dispute in this case about the safety of Aspercreme or the absence of side effects.

On February 5, 1981, FTC Complaint Counsel issued a complaint against Thompson charging unfair and deceptive advertising practices in violation of FTC Act sections 5 and 12. Following an evidentiary hearing on the

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[6] The FDA is undertaking a comprehensive review of the safety and efficacy of all OTC drugs, including trolamine salicylate. This review is not yet completed. In a February, 1983 notice of proposed rulemaking, the FDA recognized trolamine salicylate as safe but believed additional information was needed to establish efficacy. FDA, Notice of Proposed Rulemaking, External Analgesic Drug Products for Over-the-Counter Use; Tentative Final Monograph, 48 Fed. Reg. 5852 (February 8, 1983). Significant information was submitted to the FDA too late for consideration in the notice. *See id.* at 5855. The FDA continues to permit the marketing and labelling of trolamine salicylate for the temporary relief of minor arthritis pain pending a final determination of efficacy.

record, an ALJ issued his "initial decision" on June 24, 1983. Appendix D.

On November 23, 1984, the FTC issued its opinion and final order, adopting the ALJ's findings that Thompson had inaccurately represented that Aspercreme contains aspirin, Appendix B at 156a, and that Thompson had represented Aspercreme to be effective for the relief of minor arthritis pain without a reasonable basis, *id.* at 184a.[7] The issues before this Court relate only to the FTC's finding that Thompson lacked a reasonable basis for its representations of efficacy.

On the basis of this finding the FTC issued a broad order[8] of unclear scope. FTC counsel found it virtually

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[7] The FTC found that Thompson had made several efficacy claims without reasonable basis, including claims that Aspercreme was effective, that Aspercreme was as effective as orally ingested aspirin and that Aspercreme was more effective than aspirin. The FTC's analysis did not distinguish among these claims. *See* Appendix B at 161a-62a n.55.

The FTC also found that three early print advertisements that were not widely circulated had represented that Aspercreme's efficacy was scientifically established. The FTC does not purport to base the challenged portion of its order on these so-called "establishment" findings.

[8] Part II of the order would require Thompson to cease and desist from:

> A. Representing that [any OTC analgesic] product is effective for the relief of minor pain and other symptoms of any musculoskeletal disorder (such as arthritis, tendonitis, bursitis, or rheumatic disorders).
>
> B. Representing that such product is as fast as or faster than, or is as effective as, or more effective than any other drug or device in the relief of minor pain and other symptoms of any musculoskeletal disorder (such as arthritis, tendonitis, bursitis, or rheumatic disorders);
>
> unless at the time of the dissemination of any such representation, respondent possesses and relies upon a reasonable basis

impossible to define the scope of the order at oral argument before the court of appeals.[9]

Thompson appealed the FTC's decision and order to the United States Court of Appeals for the District of Columbia Circuit. Jurisdiction in the court of appeals was based on 15 U.S.C. § 45(c) & (d). The court of appeals affirmed the FTC's order on May 27, 1986 and, thereafter, denied Thompson's petition for rehearing.

The court of appeals acknowledged that Thompson "challenge[d] the FTC's order as . . . unsupported by substantial evidence," Appendix A at 2a. However, the court of appeals did not review the record evidence in the case. Most notably, it failed to review the evidence underlying "the part of [the] order that has engendered the most controversy," *id.* at 8a, Part II, the provision prohibiting efficacy claims. This part of the order was based on the FTC's unprecedented and unsupported findings that two well-controlled clinical studies are the sole acceptable reasonable basis for claims of efficacy and that Thompson's studies and a multitude of expert and public support for Aspercreme, all of which were introduced into the record, did not provide a reasonable basis for Thompson's efficacy claims.

> for such representation consisting of . . . at least two adequate and well-controlled, double-blinded clinical studies which conform to acceptable designs and protocols and are conducted by different persons, independently of each other.

Appendix C at 252a-53a. The order would also permit Thompson to advertise Aspercreme as effective if the FDA determines that it is effective. *Id.* at 253a-54a.

[9] *See* pages 21-22, *infra.*

REASONS FOR GRANTING THE WRIT

I. By Failing To Undertake Any Review of the Record as it Related to Thompson's Efficacy Claims for Aspercreme, the Court of Appeals Acted Contrary to the Settled Decisions of this Court and Affirmed an Unsupportable Cease and Desist Order.

A. Settled Decisions of this Court Require a Thorough, Probing, In-Depth Review of the Whole Record of a Challenged Agency Order.

A cornerstone of the Administrative Procedure Act is its requirement, with respect to orders based on the record of an agency hearing, that a "reviewing court *shall* . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . unsupported by substantial evidence" and that "the court *shall review* the whole record." 5 U.S.C. § 706 (emphasis added). Since 1951, it has been clear that Congress placed review of adjudicatory agency records "in the keeping of the Court of Appeals." *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 491 (1951). Congress "has left no room for doubt as to the kind of scrutiny which a court of appeals *must* give the record before [an agency] to satisfy itself that the [agency's] order rests on adequate proof." *Id.* at 487 (emphasis added).

Specifically, adjudicatory orders must be reviewed "in the light that the record in its entirety furnishes, including the body of evidence opposed to the [agency's] view." *Id.* at 488. "The substantiality of evidence must take into account whatever in the record fairly detracts from its weight." *Id.* Moreover, the review of an agency record must be "a thorough, probing, in-depth review." *Citizens To Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971) (describing factual review requirements under the less rigorous "arbitrary and capricious" standard).

The standard of review of agency orders set forth in *Universal Camera* applies to FTC orders, such as the

cease and desist order in this case, under section 5(c) of the Federal Trade Commission Act, 15 U.S.C. § 45(c). *FTC v. Standard Oil Co.*, 355 U.S. 396, 401 n.6 (1958); *accord FTC v. Indiana Fed'n of Dentists*, 106 S.Ct. 2009, 2015 (1986). It follows that the total failure to review key agency findings is an abdication of statutory duty and a gross misapplication [10] of the required standard that this Court should not condone or leave to be repeated in other cases.

B. The Court of Appeals Failed To Review the Record Behind the FTC's Decision that Thompson's Efficacy Claims for Aspercreme Lacked Reasonable Basis.

Despite the foregoing well settled principles of judicial review and despite the fact that a key element of Thompson's case on appeal was the absence of record support for the FTC's central findings that Thompson's Aspercreme efficacy claims lacked a reasonable basis, the court of appeals did not review the record support for those findings. The court's failure to comply with its statutory mandate and with the directions of this Court is manifest on the face of its decision.

The court of appeals admitted that the FTC never before required two well-controlled clinical studies to support the simple kind of efficacy claims made by Thompson for Aspercreme. However, rather than reviewing the record relied upon by the FTC for its determination that the facts of this case warranted a departure from all prior precedent, the court merely commended the FTC for applying the proper factors. Moreover, the court failed to review the record relied upon by the FTC for its determination that the numerous studies possessed by Thompson did not provide a reasonable basis for Thompson's efficacy claims.

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[10] *See FTC v. Standard Oil Co.*, 355 U.S. 396, 401 (1958) (Supreme Court will intervene when the substantial evidence standard "appears to have been misapprehended or grossly misapplied.").

1. *The Court of Appeals Failed To Review the Record Underlying the FTC's Factual Determination that the Only Basis it Would Deem "Reasonable" for Any Claim that Aspercreme Works Is Two Well-Controlled Clinical Studies.*

The FTC's determination that "Thompson should possess two well-controlled clinical tests to have a reasonable basis for its Aspercreme efficacy claims," Appendix B at 165a-66a, is integral to both the finding of liability and to the scope of the FTC's order.

In determining the level of support needed to provide a reasonable basis for Thompson's statements, the FTC applied what it viewed as the facts of the case to six factors derived from its previous cases of *In re Pfizer, Inc.*, 81 F.T.C. 23 (1972), and *In re National Dynamics Corp.*, 82 F.T.C. 488 (1973).[11] FTC argued before the court of appeals that the application of the *Pfizer* factors was a "factual finding" to be reviewed under the substantial evidence standard.[12] The court of appeals similarly stressed the factual nature of the inquiry.[13] Thompson explicitly argued that the record did not support the

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[11] The factors, identified in a recent FTC policy statement, *see* Appendix B at 231a-45a, include consideration of "(1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable." *Id.* at 163a-64a.

[12] Brief for Respondent Federal Trade Commission at 24 & n.21, *Thompson Medical Co.*, 791 F.2d 189 (D.C. Cir. 1986) (hereinafter "FTC Brief").

[13] "The controversy thus turns on whether the FTC has properly applied the law to the facts." Appendix A at 23a. "[T]he Commission . . . determined that the particular facts here warranted the imposition of a clinical testing requirement." *Id.* at 24a.

FTC's two well-controlled clinical test reasonable basis standard.[14]

Nevertheless, the court of appeals failed to conduct the necessary inquiry into the challenged findings. The relevant portion of the court's opinion appears at pages 16a-28a of Appendix A. Nowhere in the opinion is there any discussion of the evidence on which the FTC's standard was based. Nor is there any finding that the facts on which the FTC's analysis was based were supported by substantial evidence in the record as a whole.[15] Instead, the court of appeals merely stated that it "decline[d] to interfere with [the FTC's] exercise of that discretion in the circumstances of this case." Appendix A at 28a.

This Court has made clear that expertise and discretion are not a permissible substitute for substantial evidence in the record as a whole.[16] As this Court stated in *Baltimore & Ohio R.R. Co.*,

> [i]f we were to reverse the District Court, we would in effect be saying that the expertise of the Commission is so great that when it says the average territorial costs fairly represent the costs of North-South traffic, the controversy is at an end, even though the record does not reveal what the nature of that North-South traffic is. The *require-*

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[14] Brief of Petitioner Thompson Medical Company, Inc., at 21-30, *Thompson Medical Co.*, 791 F.2d 189 (D.C. Cir. 1986) (hereinafter "Opening Brief").

[15] While the court commended the FTC's catalog and analysis of the relevant factors and declared that the use of the factor analysis is "well-founded in precedent," *see* Appendix A at 22a, the *underlying facts* on which the FTC's analysis was based were left wholly unexamined.

[16] *See, e.g., Baltimore & O.R.R. Co. v. Aberdeen & R.R.R.*, 393 U.S. 87, 91-92 (1968); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167 (1962); *cf. Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 48 (1983) (applying rationale of *Burlington Truck Lines* in the context of rulemaking).

> *ment for administrative decisions based on substantial evidence and reasoned findings*—which also make effective judicial review possible—*would become lost in the haze of so-called expertise. . . . That is impermissible under the Administrative Procedure Act.*

393 U.S. at 91-92 (emphasis added); *see Burlington Truck Lines*, 371 U.S. at 167 ("unless we make the requirement for administrative action strict and demanding, *expertise*, the strength of modern government, can become a monster which rules with no practical limits on its discretion.").

Close scrutiny of the FTC's findings and analysis is particularly necessary in this case where, for the first time, and contrary to prior decisions, the FTC found, required and ordered that the *only* reasonable basis for *any* efficacy claim must be two well-controlled clinical tests.[17] Previously, the FTC had limited the two well-controlled clinical test requirement to advertising claims that efficacy was medically proven or scientifically established (so-called "establishment claims"). *See, e.g.*, Appendix A at 22a; *In re Sterling Drug, Inc.*, 102 F.T.C. 395, 762, 778 (1983), *aff'd*, 741 F.2d 1146 (9th Cir. 1984), *cert. denied*, 105 S. Ct. 1843 (1985). In *Pfizer*, a case involving an external sunburn analgesic, the FTC had rejected Complaint Counsel's contentions that the only reasonable basis for efficacy claims was adequate and well-controlled clinical tests. 81 F.T.C. at 68. The FTC stated:

> [T]o take the position that a particular type of test must be made, wholly disregards the value of the clinical experience of a number of experts in the

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[17] *Cf. Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 42 (explaining additional burden on agency that changes its course); *Atchison, T. & S.F. Ry. v. Wichita Bd. of Trade*, 412 U.S. 800, 808-817 (carefully reviewing attempt by ICC to justify change by asserting factual distinctions).

> dermatology field of medicine such as those called by respondent. Moreover, such a position would appear to repudiate clinical experience entirely and to insist that laboratory testing be substituted in all instances where advertising is involved.

Id. at 67-68 (quoting ALJ).

In two subsequent cases involving internal analgesics the FTC found that the two well-controlled clinical test standard should be applied only to establishment claims. *See Sterling Drug* at 762-63, 776-77 & n.43; *In re Bristol-Myers Co.*, 102 F.T.C. 21, 349-51 (1983), *aff'd*, 738 F.2d 544 (2d Cir. 1984), *cert. denied*, 105 S. Ct. 960 (1985). As the FTC recognized in *Bristol-Myers*, the claim " 'Our product works better than aspirin,' and the claim, 'Scientific tests *prove* that our product works better than aspirin' " are not the same. 102 F.T.C. at 350. Requiring the same substantiation for both would imply the "somewhat counterintuitive" proposition that consumers would interpret the claims the same way. *Id.*; *see Sterling Drug*, 102 F.T.C. at 777. Although the FTC recognized that in some cases evidence might be presented "that consumers did expect unequivocal scientific proof even when the advertisements made no express or implied reference to such proof," *Bristol-Myers*, 102 F.T.C. at 351, no such evidence was presented in this case.

By equating establishment claims and non-establishment claims in this case, the FTC has departed from the conclusions reached in its previous cases.

As discussed below, *see* Part I.C., *infra*, the key findings underlying the FTC's application of the *Pfizer* factors were not supported on the record as a whole. Thus, the analysis of the factors was fatally flawed. Thompson is entitled to judicial review of the record on which the FTC's findings were based. The court of appeals' failure to undertake this review has left the FTC free to apply its new substantiation requirement unbridled by any check on its discretion.

2. *The Court of Appeals Failed To Review the Record Underlying the FTC's Factual Determination that Thompson Lacked Two Well-Controlled Clinical Studies.*

The court of appeals also refused to determine whether the record supported the FTC's conclusion that the clinical tests presented by Thompson were not adequate. The court's discussion of the issue is devoid of any consideration of the record evidence or of any findings with respect to the substantiality of that evidence. *See* Appendix A at 30a-31a.

Rather than satisfy its statutory obligation to examine the record, the court claimed that "Thompson does not argue that the FTC's decision was unsupported by substantial evidence in the record." *Id.* at 30a. This statement is demonstrably incorrect and is contradicted by the court's earlier assertion that "Thompson challenges the FTC's order as . . . unsupported by substantial evidence." *Id.* at 2a.

The court of appeals recognized that "Thompson devotes much time and energy to a discussion of the scientific and technical material that was put into evidence in this matter." *Id.* at 30a. Indeed, Thompson explicitly claimed that "the substantial weight of the evidence of record does not support the order herein," Opening Brief at 6 (summary of argument), and explored at length the record evidence supporting the studies on which it relied to demonstrate that the record did not support the FTC's disregard of Thompson's studies. *Id.* at 30-32, 34, 38-41.

Thompson explicitly argued the oft-repeated formulation of the substantial evidence test—that "[t]he FTC order is not supported by 'such relevant evidence as a reasonable man might accept as adequate to support the

conclusion.' " [18] Moreover, at oral argument, the court asked counsel for Thompson if "you understand our job is not to determine what the weight of the evidence is but merely is there substantial evidence in the record to support the Commission's findings." Counsel responded "Yes, I understand that, Judge Ginsburg. We feel it is an abuse of discretion below." Appendix G at 696a.

Thompson seeks review of the failure of the court of appeals to carry out its statutory duty.

C. The Court of Appeals' Failure To Review the Record Was Prejudicial Error.

The issue before the FTC was whether Thompson had a reasonable basis for believing its non-establishment efficacy claims to be true. *See, e.g., Pfizer*, 81 F.T.C. at 64; *National Dynamics*, 82 F.T.C. at 552-53. The FTC's prior decisions did not suggest that Thompson was being unreasonable in relying on its wealth of clinical and marketing experience and on the studies it had reviewed. Indeed, as noted above, the FTC had previously suggested that just such information could provide a reasonable basis for non-establishment efficacy claims. *See* pages 13-14, *supra*.

Instead of considering the wealth of information available to Thompson, the FTC purported to apply its *Pfizer* factors to reach the unprecedented conclusion that only two well-controlled clinical tests would provide a reasonable basis for any Aspercreme efficacy claim. The facts on which the FTC relied in its analysis of the applicability of the *Pfizer* factors to this case are not supported by substantial evidence in the record. The failure of the court of appeals to review that record was prejudicial error.

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[18] Reply Brief of Petitioner Thompson Medical Company, Inc. at 22, *Thompson Medical Co.*, 791 F.2d 189 (D.C. Cir. 1986) (quoting *Steadman v. SEC*, 450 U.S. 91, 99 (1981)); *see, e.g., FTC v. Indiana Fed'n of Dentists*, 106 S.Ct. 2009, 2015 (1986).

Among the key findings that were not supported by substantial evidence in the record as a whole were findings that:

(1) despite the overwhelmingly favorable responses of more than 65,000 consumers and more than 1,000 health care professionals, consumers were unable to evaluate Aspercreme's efficacy;

(2) cessation of truthful Aspercreme advertising would not harm arthritis sufferers because an alternative, non-aspirin external analgesic would likely be developed (at some unspecified future time) to fill the void left by Aspercreme;

(3) two well-controlled clinical studies would be easy and inexpensive to complete; [19]

(4) the use of Aspercreme, which costs approximately three dollars for the regular three ounce size and is sold with a full money back guarantee, could cause significant economic harm to consumers.[20] This finding is particularly significant because the FTC found no cognizable health or safety risk from Aspercreme use. In the absence of any significant economic harm to consumers, there is no justification for re-

[19] The FTC finding directly contradicted the FDA's expert panel on external analgesics, which found "[c]ontrolled clinical studies [for external analgesics] are difficult to perform for symptoms that are frequently fleeting and usually self-limiting, and the Panel is especially aware that it would be almost impossible to interest investigators in such studies." 44 Fed. Reg. 69768, 69786 (December 4, 1979).

[20] The FTC's finding of economic harm was based on a finding by the ALJ. Appendix B at 174a. Neither the FTC nor the ALJ, however, made any finding based on the costs of Aspercreme use. Rather, they attempt to charge Aspercreme with the costs of all unproven or fraudulent arthritis remedies. *See* Appendix D at 447a-49a. Moreover, much of the ALJ's finding is based on societal costs that would result from the continued use of Aspercreme even if ineffective. *Id.* The FTC specifically rejected this possibility. Appendix B at 174a-76a.

quiring a specific type of rigorous scientific proof as a basis for non-establishment efficacy claims;

(5) experts would consider two well-controlled clinical studies to be the only reasonable basis supporting claims of efficacy.[21]

In sum, facts relied upon by FTC in its analysis of the applicability of virtually each of the *Pfizer* factors to this case were unsupported by substantial evidence on the record as a whole.[22] The lack of support for any one

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[21] By examining the degree of proof required by scientists to *prove efficacy*, rather than the basis scientists would *consider reasonable for making efficacy claims, see, e.g.*, Appendix B at 179a; Appendix D at 451a, the FTC pre-ordained its conclusion that the sole reasonable basis for even non-establishment claims was proof of scientific establishment. This is the very result the FTC had declined, for strong reasons, to reach in *Pfizer* and *Bristol-Myers*.

The FTC presented two expert witnesses on the medical issues. One had previously published a book stating "the only reliable measurement of efficacy and safety remains clinical practice and observation." He acknowledged that clinical practice and observation, on which Thompson had relied, could be a reliable measure of efficacy. The other had gone so far in his commitment to a clinical testing requirement that he had dissented from the FDA expert external analgesic panel's recommendation that certain external analgesic products could be declared effective without clinical tests. *See* 44 Fed. Reg. at 69785-86, 69789. Several well-qualified, independent experts maintained that numerous factors could provide a reasonable basis for efficacy claims.

[22] Moreover, the facts in *Bristol-Myers* and *Sterling Drug* each more strongly pointed toward requiring two well-controlled clinical studies than the facts of this case. In those cases, the drug product was taken internally and posed health risks. The claims were less capable of consumer evaluation. There were already a wide variety of similar products in a highly competitive market. Clinical tests were likely to be no more costly or difficult to perform. There were health risks from false claims and, as a result, experts would have considered greater substantiation necessary. Yet, in those cases, the FTC declined to find that "reasonable basis" for *any* claim (including non-establishment claims) could be shown *only* by two well-controlled clinical studies.

factor would invalidate the FTC's ultimate determination. The court of appeals failed to review the record underlying any of the factors.

The FTC's conclusion with respect to the reasonable basis standard infected its entire analysis of Thompson's reasonable basis. As a result of its unsupported conclusion, the FTC was able to ignore Thompson's overwhelming clinical and consumer evidence and the studies reasonably relied upon by Thompson.

Moreover, Thompson provided extensive evidence of several well-controlled clinical tests and expert testimony in support of the adequacy of those tests. The record, viewed as a whole, does not support the FTC's rejection of those studies.[23] Nor may the FTC claim special expertise in evaluating clinical tests. The FTC has expressly recognized its limits in this regard:

> The nature and intricacy of the debate on the adequacy of [the well-controlled test there at issue] leads to the view that the Commission's role should simply be one of attempting to determine the existence and general quality of the tests and a threshhold determination as to the reasonableness of reliance thereon, rather than an attempt to conclusively determine the adequacy of the tests.

Pfizer, 81 F.T.C. at 67 n.22. Despite the FTC's admitted lack of expertise, the court of appeals failed to review the record relating to Thompson's studies.

* * * *

Key FTC findings and conclusions are not supported by substantial evidence in the record as a whole. The

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[23] The FTC's primary reliance on the FDA's analysis of the tests is misplaced. The FDA's analysis did not consider either the substantial evidence on the tests which had been submitted to FDA too late for consideration but which were offered for inclusion in the FTC record.

critical Part II of the order is based on those findings. Thompson was entitled to review of that record by the court of appeals. The failure of the court of appeals to undertake that review should be reviewed by this Court.

II. The Order, Which Will Inhibit Even Unassailably Truthful Advertising, Is Vague and Overbroad.

Ever since the enactment of the 1959 amendments to the FTC Act, which imposed severe penalties for the violation of a final cease and desist order, this Court has made clear that vague orders are intolerable. "[A]n order's prohibitions should be clear and precise in order that they may be understood by those against whom they are directed." [24] Shortly after the enactment of the 1959 amendments, this Court observed "The severity of possible penalties prescribed by the amendments for violations of orders which have become final underlines the necessity for fashioning orders which are, at the outset, sufficiently clear and precise to avoid raising serious questions as to their meaning and application." *FTC v. Henry Broch & Co.*, 368 U.S. 360, 367-68 (1962).

Vagueness is particularly intolerable where the order is broad. *See American Home Prods.*, 695 F.2d at 710. Moreover, where an FTC order "is capable of reaching expression sheltered by the First Amendment, the doctrine demands a greater degree of specificity than in other contexts." [25] "The First Amendment does not per-

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[24] *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965) (quoting *FTC v. Cement Institute*, 333 U.S. 683, 726 (1948)); *see American Home Prods. Corp. v. FTC*, 695 F.2d 681, 710-711 (3d Cir. 1982) (striking down as vague part of an FTC cease and desist order requiring a "reasonable basis" for OTC analgesic claims).

[25] *Smith v. Goguen*, 415 U.S. 566, 573 (1974) (discussing flag contempt statute); *cf. Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972) ("[W]here a vague statute 'abut[s] upon sensitive areas of basic First Amendment freedoms,' it 'operates to inhibit the exercise of [those] freedoms.' ").

mit a remedy broader than that which is necessary to prevent deception."[26]

Part II(A) of the FTC order in this case, broadly prevents Thompson from "representing that [any OTC analgesic drug] is effective for the relief of minor pain" without two well-controlled clinical tests. This is impermissibly vague. Not even FTC counsel, at argument before the court of appeals, was able to identify what advertising claims would imply efficacy. Given the broad interpretation suggested by FTC counsel, the order goes far beyond that which is necessary to prevent deception and would prohibit even truthful, non-deceptive advertisement of Aspercreme's purpose and of consumer satisfaction.

A substantial percentage of oral argument before the court of appeals concerned this inability to ascertain the scope of the order. *See* Appendix G at 701a-05a, 714a, 723a-32a, 735a-39a, 742a-49a. After pointing out that the scope of Part II(a) is "a major problem," Thompson's counsel argued that "if you read it, it says we can't do anything" and that the prohibition "is very ambiguous." *Id.* at 702a. Counsel also stated Thompson's belief "that there is a First Amendment problem because . . . there is no reason to stop all advertising when a narrower restriction will do." *Id.* at 714a.

Similarly the court expressed great discomfort with the scope and ambiguity of the order. In an extended colloquy occupying much of FTC counsel's argument, the court repeatedly asked what Thompson could lawfully say about Aspercreme. FTC counsel was unable to explain the scope of the order and ultimately was forced to take the position that the order might prohibit virtually any

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[26] *National Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 164 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978) (striking down portion of FTC order); *Beneficial Corp. v. FTC*, 541 F.2d 611, 618-20 (3d Cir. 1976), *cert. denied*, 430 U.S. 983 (1977) (same).

representation linking Aspercreme to minor arthritis pain.[27]

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[27] QUESTION: Could they say that? Could they say, "This will make you feel better"?

MR. ORLANS: Well, I think that raises some interesting issues and I am not comfortable standing here and pontificating on them. I think—

QUESTION: I am not comfortable with that part of the order, frankly. I don't know what it means.

MR. ORLANS: Which is that, Your Honor?

QUESTION: The part you were just referring to, IIA. What does it mean?

QUESTION: That is what concerns me, too. Appendix G at 724a-25a.

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QUESTION: Counsel, let me stop you. There are hundreds of creams on the market that advertise, their advertising does all kinds of things, creams that are advertised as being soothing. Of course, we have no problem with somebody who says it soothes.

MR. ORLANS: No, Your Honor.

QUESTION: It makes you feel better?

MR. ORLANS: Well, I suppose that the less objective the claim is, the less need there is to substantiate it. Now, from the standpoint of a drug product, I suppose that I have some questions as to how consumers would interpret a claim of "makes you feel better." I am not really comfortable standing here pontificating on that issue. *Id.* at 728a-29a.

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QUESTION: But again, it either has to—that means a specific direction it is supposed to take, could they say, "Sufferers of arthritis, this is a cooling creme"?

MR. ORLANS: I think that is beginning to infringe on the order, Your Honor. Again, without the consumer survey evidence, I can't stand here and tell you that consumers would interpret that to mean that it would relieve arthritis symptoms, but I suspect that it might, and that is a claim that the order would prohibit until such time as it was substantiated. *Id.* at 731a-32a.

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QUESTION: How about relief from arthritic pain? It seems to me I have seen that expression advertised.

MR. ORLANS: Well, I think if all that is said is that the product is for the relief of arthritic pain, the implications would be that it works pharmacologically in some fashion, it gets into the blood, it gets into the body. If it just says it is a rub—

Interpreted in this extraordinarily broad manner, the order would chill a wide variety of clearly true and non-deceptive advertising claims. For example, Thompson would be taking a severe risk to claim that "Satisfied consumers have made Aspercreme rub their second choice for the external relief of minor arthritis pain," or that "Hundreds of thousands of minor arthritis pain sufferers rely on Aspercreme for temporary relief." These are truthful, non-deceptive factual statements that are not amenable to proof by two well-controlled clinical tests. The risk would still exist even if Thompson added that "the FDA has not yet certified the active ingredient in Aspercreme to be effective," or even that "FDA has determined that data is not available demonstrating that Aspercreme is effective."

Such a broad and vague order infringes upon Thompson's First Amendment rights and will prevent the flow of valuable information to the millions who suffer from minor arthritis pain. "There is no longer any room to doubt that what has come to be known as 'commercial speech' is entitled to the protection of the First Amendment." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 105 S. Ct. 2265, 2274-75 (1985). As this Court

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QUESTION: I am having the same problem here that my colleagues are having. What can they say?

MR. ORLANS: Well, I think there are a couple of possibilities. One is to simply put the product on the shelves and rely on the fact that people have been using it, and that frankly is how most of these products are sold, most of the triethanolamine salicylate products, but—

QUESTION: Some would like to have a better alternative. . . .

QUESTION: But they can't say anything as to the use for which it is designed?

MR. ORLAN: I think that, as Judge Mikva—

QUESTION: You aren't going to buy anything if you don't know what the thing is supposed to do.

MR. ORLANS: Of course the label would say that, Your Honor, but we could certainly allow it to be advertised as a rub. *Id.* at 737a-39a.

noted in the context of professional advertising, which has a "particularly strong" potential for deception, "restrictions upon such advertising may be no broader than reasonably necessary to prevent the deception." [28] "[T]he States may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive." [29] The order here does just that.

Part II(A) of the FTC order is not sufficiently clear to fairly apprise Thompson of its scope. Under fear of penalty, until it successfully completes two adequate and well-controlled double blinded clinical tests satisfying the FTC's strict requirements, Thompson will be precluded from communicating truthful non-deceptive information to the public. This Court should review Part II(A) of the order.

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[28] *In re RMJ*, 455 U.S. 191, 203 (1982); *see National Comm'n on Egg Nutrition*, 570 F.2d at 164; *Beneficial Corp.*, 542 F.2d at 619-20.

[29] *In re RMJ*, 455 U.S. at 203.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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